

What Is Claimed Is:

1. A pharmaceutical composition, comprising:
 - (1) a KGF-2 polypeptide in a concentration range of about 0.02 to about 40 mg/ml (w/v);
 - (2) a buffer having a buffering capacity of between about 5.0 and about 8.0 at a concentration range of about 5 mM to about 50 mM; and
 - (3) a pharmaceutically acceptable diluent to bring the composition to a designated volume;or a reaction product thereof.
2. The pharmaceutical composition of claim 1, further comprising:
 - (1) a chelating agent at a concentration range of about 1 mM to about 10 mM; and
 - (2) NaCl at a concentration range of about 0.1 mM to about 150 mM.
3. The pharmaceutical composition of claim 1, further comprising one of:
 - (1) about 0.5% to about 2% w/v glycerol,
 - (2) about 0.1% to about 1% w/v methionine, or
 - (3) about 0.1% to about 2% w/v monothioglycerol.
4. The pharmaceutical composition of claim 1, wherein said KGF-polypeptide is present in a concentration range of about 0.05 to about 30 mg/ml (w/v).
5. The pharmaceutical composition of claim 4, wherein said KGF-polypeptide is present in a concentration range of about 0.1 to about 20 mg/ml (w/v).

6. The pharmaceutical composition of claim 5, wherein said KGF-polypeptide is present in a concentration range of about 0.2 to 4 mg/ml.

7. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is KGF-2-Δ33.

8. The pharmaceutical composition of claim 1, wherein said diluent is water.

9. The pharmaceutical composition of claim 2, wherein said chelating agent is EDTA at a concentration of about 1 mM, and said NaCl is present at a concentration of about 125 mM.

10. The pharmaceutical composition of claim 1, wherein said pH is from about pH 5.5 to about pH 6.5.

11. The pharmaceutical composition of claim 10, wherein said pH is about pH 6.2.

12. The pharmaceutical composition of claim 1, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

13. The pharmaceutical composition of claim 12, wherein said buffer is a phosphate, acetate or citrate salt.

14. The pharmaceutical composition of claim 13, wherein said buffer is a citrate salt.

15. The pharmaceutical composition of claim 1, wherein said buffer is present in a concentration range of about 5 mM to about 30 mM.

16. The pharmaceutical composition of claim 15, wherein said buffer is a citrate salt present in a concentration of from about 10 mM to about 20 mM.

17. The pharmaceutical composition of claim 1, further comprising a stabilizing amount of one or more of (a) an antioxidant or (b) a thiol-compound.

18. The pharmaceutical composition of claim 1, wherein said composition is maintained at a temperature at or below -20°C.

19. The pharmaceutical composition of claim 1, comprising:

- (1) 2 mg/ml KGF-2 Δ 33 polypeptide (w/v);
- (2) 20 mM sodium citrate;
- (3) 125 mM NaCl;
- (4) 1 mM EDTA; and
- (5) water as diluent, or
a reaction product thereof.

20. A pharmaceutical composition, comprising:

- (1) a KGF-2 polypeptide in a concentration range of about 0.02 to about 40 mg/ml (w/v);
- (2) a buffer having a buffering capacity of between about 5.0 and about 8.0 at a concentration range of about 5 mM to about 50 mM;
- (3) a bulking agent; and
- (4) a pharmaceutically acceptable diluent to bring the composition to a designated volume;
or a reaction product thereof.

21. The pharmaceutical composition of claim 20, wherein said bulking agent is selected from the group consisting of sucrose, glycine, mannitol, trehalose, and mixtures thereof.

22. The pharmaceutical composition of claim 1, further comprising:

- (1) a chelating agent at a concentration range of about 1 mM to about 10 mM; and
- (2) NaCl at a concentration range of about 0.1 mM to about 125 mM.

23. The pharmaceutical composition of claim 21, wherein said bulking agent is sucrose or a mixture of sucrose and glycine.

24. The pharmaceutical composition of claim 21, wherein said bulking agent is present in a concentration of about 2% to about 10% w/v.

25. The pharmaceutical composition of claim 21, wherein said bulking agent is 5% mannitol, 7% sucrose, 8% trehalose, or 2% glycine + 0.5% sucrose.

26. The pharmaceutical composition of claim 20, wherein said pH is about pH 6.2.

27. The pharmaceutical composition of claim 20, wherein said diluent is water.

28. The pharmaceutical composition of claim 20, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

29. The pharmaceutical composition of claim 28, wherein said buffer is a phosphate or citrate salt.

30. The pharmaceutical composition of claim 29, wherein said buffer is a citrate salt.

31. The pharmaceutical composition of claim 27, wherein over 90% of the water is removed by lyophilization.

32. The pharmaceutical composition of claim 31, which is reconstituted in with an amount of sterile water effective to maintain isotonic conditions of 290 mOsm.

33. The pharmaceutical composition of claim 20, wherein said KGF polypeptide is KGF-2-Δ33.

34. The pharmaceutical composition of claim 20, wherein said buffer is added in a concentration from about 5 mM to about 50 mM

35. The pharmaceutical composition of claim 34, wherein said buffer is citrate at a concentration of about 10 mM.

36. The pharmaceutical composition of claim 20, further including a stabilizing amount of one or more of (a) an antioxidant, or (b) a thiol-compound.

37. The pharmaceutical composition of claim 31, wherein said composition is reconstituted in sterile water containing a stabilizing amount of an antioxidant comprising: a) about 0.01% to about 2% w/v monothioglycerol, b) about 0.01% to about 2% w/v ascorbic acid, c) about 0.01% to about 2% w/v methionine or d) combinations thereof.

38. A pharmaceutical composition, comprising:

(1) a KGF-2 polypeptide in a concentration range of about 0.02 to about 40 mg/ml (w/v);

(2) an effective amount of citric acid or a pharmaceutically acceptable salt thereof, at a concentration range of about 5 mM to about 20 mM;

- (3) NaCl at a concentration range of about 0 mM to about 125 mM,
- (4) EDTA at a concentration range of about 1 mM to about 10 mM and
- (5) one or more of sucrose, mannitol, glycine or trehalose at a concentration range of about 2% w/v to about 15% w/v; and
- (6) water.

39. The pharmaceutical composition of claim 38, wherein said KGF-2 polypeptide is present at a concentration of about 2 mg/ml, about 4 mg/ml, or about 10 mg/ml.

40. The pharmaceutical composition of claim 38, wherein over 90% of the water is removed by lyophilization.

41. The pharmaceutical composition of claim 1, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

42. The pharmaceutical composition of claim 20, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

43. The pharmaceutical composition of claim 41, wherein said thickening agent is present in an amount effective to raise the viscosity to about 50 to about 1,000 cps.

44. The pharmaceutical composition of claim 43, wherein said thickening agent in an amount effective to raise the viscosity to about 200 to about 300 cps.

45. The pharmaceutical composition of claim 41, wherein said thickening agent is present in a concentration of 0 to 5% (w/w).

46. The pharmaceutical composition of claim 41, wherein said thickening agent is a water soluble etherified cellulose or a high molecular weight polymer of acrylic acid cross-linked with allylsucrose or an allyl ether of pentaerythritol.

47. The pharmaceutical composition of claim 46, wherein said etherified cellulose is an alkyl cellulose, hydroxyalkyl cellulose, carboxyalkyl cellulose or alkylhydroxyalkyl cellulose.

48. The pharmaceutical composition of claim 41, wherein said etherified cellulose is methylcellulose, hydroxyethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose.

49. The pharmaceutical composition of claim 47, wherein said etherified cellulose derivative has a molecular weight of about 50,000 to about 700,000 and is present in a concentration of about 0 to about 20% by weight.

50. The pharmaceutical composition of claim 49, wherein said etherified cellulose derivative has a molecular weight of about 80,000 to about 240,000 and is present in a concentration of about 2% to about 8% by weight.

51. The pharmaceutical composition of claim 42, wherein said buffer is citrate in a concentration of about 10 mM to about 50 mM.

52. The pharmaceutical composition of claim 51, wherein said buffer is citrate in a concentration of about 10 mM to about 20 mM citrate.

53. The pharmaceutical composition of claim 51, wherein said bulking agent is sucrose in a concentration of about 0% to about 5% sucrose.

54. The pharmaceutical composition of claim 53, wherein said thickening agent is added directly to a liquid formulation and thereafter lyophilized.

55. The pharmaceutical composition of claim 53, wherein said thickening agent is added to a lyophilized formulation by reconstituting said formulation by adding a suitable diluent having a thickening agent dissolved therein.

56. A thickened KGF-2 polypeptide solution composition formed by mixing:

- (1) a topically effective amount of a KGF polypeptide;
- (2) about 10 mM to about 500 mM sodium citrate buffer;
- (3) about 0.1 to about 150 mM NaCl;
- (4) 1 mM EDTA;
- (5) about 0.1 to about 7% sucrose;
- (6) about 0.75 to about 1.5% (w/w) carboxy methyl cellulose or about 0.5 to about 1.5% hydroxy propyl methyl cellulose or about 0.25 to about 0.75% hydroxy ethyl cellulose or about 0 to 1% carbomer or any combination thereof.

57. The composition of claim 1, further comprising a gelling agent in an amount effective to raise the viscosity to about 0 to about 10,000 cps at room temperature.

58. The composition of claim 20, further comprising a gelling agent in an amount effective to raise the viscosity to about 0 to about 10,000 cps at room temperature.

59. The composition of claim 57, wherein said gel forming agent is a water-soluble polymer capable of forming a viscous aqueous solution, or non-water soluble, water-swellaable polymer capable of forming a viscous solution.

60. The composition of claim 59, wherein said gel forming agent is a high molecular weight polymer selected from the group consisting of vinyl polymer, polyoxyethylene-polyoxypropylene copolymer, polysaccharide, protein, poly(ethylene oxide), acrylamide polymer or a salt thereof.

61. The composition of claim 60, wherein said gel forming agent is (1) a vinyl polymer selected from the group consisting of polyacrylic acid, polymethacrylic acid, polyvinyl pyrrolidone polyvinyl alcohol, and salts and esters thereof; or (2) a polysaccharide selected from the group consisting of a cellulose derivative, a glycosaminoglycan, agar, pectin, alginic acid, dextran, α -amylose, amylopectin, chitosan, and salts esters thereof.

62. The composition of claim 60, wherein said gel forming agent is a glycosaminoglycan selected from the group consisting of hyaluronic acid, chondroitin, chondroitin-4-sulfate, heparan sulfate, heparin and salts and esters thereof.

63. The composition of claim 62, wherein said glycosaminoglycan is present in combination with collagen, gelatin, or fibronectin.

64. The composition of claim 60, wherein said gel forming agent is an acrylamide polymer selected from the group consisting of a polyacrylamide or a polymethacrylamide.

65. The composition of claim 60, wherein said gel forming agent is a polyoxyethylene-polyoxypropylene block copolymer.

66. The composition of claim 65, which comprises about 10 to about 60% by weight of a polyoxyethylene-polyoxypropylene block copolymer having an average molecular weight of about 500 to 50,000.

67. The composition of claim 66, which comprises about 14 to about 18% by weight of a polyoxyethylene-polyoxypropylene block copolymer having a molecular weight in the range 1,000 to 15,000.

68. The composition of claim 67, wherein said gel forming agent is a polyoxyethylene-polyoxypropylene block copolymer is Pluronic F108, Pluronic F127, or Poloxamer 407.

69. The composition of claim 1, wherein said KGF-2 polypeptide is present in a concentration of about 0.01 mg/ml to about 10 mg/ml.

70. The composition of claim 57, wherein said composition is formed by mixing:

- (1) a KGF-2 polypeptide, in a final calculated concentration of 0.01 mg/ml to about 10 mg/ml;
- (2) an effective amount of a buffering agent;
- (3) about 10% to about 60% by weight of a polyoxyethylene-polyoxypropylene block copolymer having an average molecular weight of about 500 to 50,000; and
- (4) a pharmaceutically acceptable diluent, preferably water.

71. The composition of claim 70, wherein polyoxyethylene-polyoxypropylene block copolymer is present at a concentration of about 14% to about 18%.

72. A KGF-2 gel formulation, comprising:

- (1) a pharmaceutically active amount of KGF-2 polypeptide;
- (2) about 10 mM to about 500 mM sodium citrate;
- (3) about 0.1 mM to about 150 mM NaCl;
- (4) about 1 mM EDTA;
- (5) about 0.1% to about 7% sucrose;
- (6) about 14% to about 18% Pluronic F127; and
- (7) about pH 6.2

73. A KGF-2 gel formulation, comprising:

- (1) a KGF-2 polypeptide at a concentration range of about 0.01 mg/ml to about 10 mg/ml (w/v),
- (2) sodium citrate at a concentration range of about 5 mM to about 20 mM;
- (3) about 10% to about 25% (w/v), of Pluronic 127 or Poloxamer 407; and
- (4) water to volume.

74. The gel formulation of claim 73, further comprising:

- (1) EDTA at a concentration range of about 1 mM to about 10 mM.
- (2) NaCl at a concentration range of about 0.1 mM to about 125 mM.

75. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is a N-terminal deletion selected from the group consisting of Ala (63) -- Ser (208) (KGF-2 Δ 28) and Ser (69) -- Ser (208) (KGF-2 Δ 33).

76. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is a N-terminal or C-terminal deletion mutant selected from the group consisting of Ala (39) -- Ser (208); Pro (47) -- Ser (208); Val (77) -- Ser (208); Glu (93) -- Ser (208); Glu (104) -- Ser (208); Val (123) - Ser (208); Gly (138) -- Ser (208); Met (1), Thr (36); and Cys (37) -- Lys (153).